REMARKS

THE AMENDMENT TO CLAIM 1

Claim 1(a) has been amended to emphasize that the claimed dosage form swells unrestrained dimensionally in the presence of gastric fluids. Support for the change to claim 1 is found in the specification at *inter alia*, page 14, line 21. In addition to the foregoing, in the wherein clause of claim 1, the word "taking" has been changed to --adjusting--. Support for the change to the wherein clause is found in the specification at *inter alia*, page 5, lines 5-11. As the changes to claim 1 are fully supported by the specification, no new matter has been added to the application with the amendment to claim 1.

THE ANTICIPATION REJECTION BY WONG ET AL.

Claims 1-28, 36, and 62-65 stand rejected under 35 U.S.C. § 102(b) as anticipated by Wong et al. (USPN 6,120,803). This rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565, 24 USPQ2d 1321, 1326 (Fed. Cir. 1992).

As recited in amended claim 1, the present invention relates to a sustained release oral dosage form for delivering a pharmacologically active agent to the stomach, duodenum, and upper small intestine of a patient with restricted delivery to the lower intestinal tract and colon, the dosage form comprising a therapeutically effective amount of the pharmacologically active agent incorporated in a matrix of at least one biocompatible, hydrophilic polymer that (a) swells unrestrained dimensionally in the presence of water in gastric fluid such that the size of the dosage form is sufficiently increased to provide gastric retention of the dosage form in the stomach of a patient in whom the fed mode has been induced; and (b) gradually erodes within the gastrointestinal tract over a determinable time period, wherein an optimal rate of release of the active agent from the dosage form is determined by adjusting the ratio of the erosion rate ER obtained *in vitro* for the dosage form to the dissolution rate DR obtained *in vitro* for the dosage form such that the ratio of ER to DR in the dosage form is approximately 1.2:1 to approximately 5:1.

Wong et al. teaches devices for delivering an active agent to the gastric environment over a prolonged period of time, i.e., 4 to 24 hours (col. 4, ll. 59-61 and 65). Wong et al. states that such devices should exhibit *a combination of flexibility and rigidity* so as not to be expelled from the stomach to the pyloric sphincter under fed or fasting conditions (col. 4, l. 65 to col. 5, l. 1).

In one embodiment, Wong et al. teaches an active agent dosage form for the prolonged delivery of an active agent to the stomach of a human or other animal wherein the active agent is in a polymeric matrix formed of a mixture of a swellable water soluble polymer that expands when in contact with fluids

in the gastric environment and a hydroattractant that is preferably water insoluble (col. 5, ll. 10-16). The matrix is formed *with a rigid or semi-rigid segment* in which swelling of the hydrogel is constrained to provide a rigid or semi-rigid section in the dosage form that facilitates the dosage form remaining in the stomach of a subject over a prolonged period of time (col. 5, ll. 16-21). The rigid or semi-rigid section of the dosage form comprises one or more insoluble materials, typically exhibiting low water impermeability and formed as a band circumscribing a portion of the polymer matrix (col. 5, ll. 21-27).

Wong et al. explains that *the insoluble material or band(s) prolongs the period of time in which the polymer matrix retains its integrity in an expanded state and increases the residence time of the dosage form in the stomach* (col. 5, ll. 28-32). The band limits the transport of fluid into the portion of the polymer matrix that it surrounds and provides the polymer matrix with enough rigidity to permit the dosage form to resist the compressive force of the contractions of the stomach during the housekeeping phase so that the dosage form remains in the stomach for a prolonged period of time (col. 5, ll. 32-38). As the dosage form erodes in the stomach or as active agent diffuses from the matrix, active agent is released and either absorbed by the stomach or passed from the stomach to the small intestine (col. 5, ll. 38-41).

In another embodiment, Wong et al. teaches that *the dosage form may be formed as a swellable polymer matrix attached to a separate active agent reservoir, from which the active agent is delivered* (col. 6, ll. 59-62). In this embodiment, the polymer matrix is formed as a tube or annular ring and placed about the reservoir, such that swelling of the polymer retains the active agent within the tube or ring to promote retention of the dosage form in the stomach over a prolonged period of time (col. 6, l. 62 to col. 7, l. 1). The active agent reservoir contributes to the rigidity of the dosage form such that along with the gel properties of the polymer matrix, the dosage form is retained in the stomach for a prolonged period of time (col. 7, l. 5-9).

Figures 1 to 4 of Wong et al. depict embodiments of the dosage form that require the bands and Figures 5 to 7 of Wong et al. depict the embodiments of the dosage form that require the reservoirs.

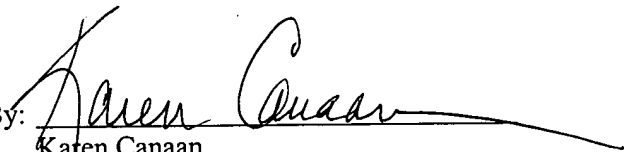
Because the Wong et al. only teaches a dosage form that is restrained, either by way of a band or a reservoir system, whereas the claimed invention expressly recites a dosage form that is not restrained, it follows that Wong et al. does not teach or suggest the claimed invention. Since the claimed invention is not anticipated by or rendered obvious by Wong et al., applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

The foregoing discussion demonstrates that the claimed invention is not anticipated by Wong et al.; accordingly, upon entry of this paper there will be no substantive rejections of the claimed invention. In light of the foregoing, upon entry of this Amendment, the claimed invention will be in condition for allowance and the non-elected species from withdrawn claims 29-35 and 37 should be subject to search and examination.

Should the Examiner have any questions or concerns regarding this paper, the Examiner is encouraged to contact the undersigned attorney at 650-251-7713 or at canaan@reedpatent.com.

Respectfully submitted,

By: 
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